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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,175	09/04/2001	Nobuhiko Ogura	Q65952	9850

7590                    06/04/2002

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
1641	5

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/944,175	OGURA, NOBUHIKO
	<b>Examiner</b>	<b>Art Unit</b>
	My-Chau T. Tran	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 March 2002.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) 23-41 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-22 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 04 September 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

## **DETAILED ACTION**

### *Election/Restrictions*

1. Applicant's election without traverse of Group I (Claims 1-22) in Paper No. 4 is acknowledged.
  
2. Claims 23-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim.  
Election was made **without** traverse in Paper No. 4.
  
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Drawings*

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "26" of figure 3 (pg. 21, line 1) and figure 12 does not exist (pg. 20, line 2). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "25" of figure 1. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 2-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a) Claims 2-22, "A" should be changed to –The– for clarity
- b) Claims 5-8 are vague and indefinite. Claims 1-4 imply that the substrate on which the probes are fixed is the same as the electrophoresis medium because no separate substrate, or electrophoresis medium is recited as being part of the claim. However, dependent claims 5-8 recite an electrophoresis medium, i.e. gel, that is adjacent to the substrate, therefore, it is unclear if the fractionating gel is the same with the fixing substrate or if they are separate and distinct media.
- c) Claims 17 and 18 are vague and indefinite because it is unclear if the labeled target is contacted with a chemiluminescent substrate prior to or after binding of the target with the probe because the claim does not positive recite such a method step. The claims

only require that the label generates chemiluminescent emission and does not positively recite exactly when such generation takes place.

d) Claim 20 is vague and indefinite with respect to the recitation of "face-like" because it is unclear what this means.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-18 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman et al. (US Patent 6,103,537).

Ullman teaches a method of capillary electroseparation specific binding assay (col. 4, lines 33-51). This method includes applying an electric potential to achieve electroseparation of the free and bound labeled species (col. 23, lines 17-38). The direction of the migration (fluid flow) is at an angle with the surface of the substrate. Since the angle as claimed in Claim 4 can be 0° to 180° with respect to the surface of the substrate. In Ullman, the angle is 0° and the direction of migration is affected by the direction or orientation of the channel formed on a surface (col. 4, lines 47-50). A member of the specific binding pair (probe) is bound to synthetic particles (substrate) (col. 5, lines 8-16). The particles are latex, organic, inorganic polymers, or lipid bilayers (col. 13, lines 29-53). The analyte (target) is antigens, antibodies, ligands, or DNA (col. 6, lines 2-15). A label can be bound or unbound to a specific binding pair (col. 11, lines 12-

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30; col. 9 lines 25-46). The label can be a dye, enzyme, fluorescent molecule or chemiluminescent molecule. The binding determination can be performed qualitatively or quantitatively (col. 20, lines 7-21). The method further discloses employing sieving gel in the electroseparation medium to assist in providing localization of the bound complex and achieves appropriate separation of free and bound species (col. 24, lines 31-40).

Ullman discloses examples of assays in which the method can apply to (col. 26, lines 61-67 to col. 27, lines 1-12). In one such example, the method is applied to a competitive receptor-ligand binding assay in which pre-conjugated receptor-beads are employed (col. 28, lines 31-53). In which case the receptor, tracer, and test compound are allowed to incubate in a flow configuration, the mixture is moved through a region of a microchannel in which magnetic beads are located. The magnetic beads selectively capture the membrane-bound receptors and are immobilized by applying a magnetic field. The free fluorescent tracer in the supernatant and the bound fluorescent tracer in the solid phase are measured.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ullman et al. (US Patent 6,103,537) in view of Hassard et al (US Patent 6,103,533).

The method of Ullman is disclosed above.

Ullman differs from the claimed invention in failing to include a method of two-dimensional scanning and three-dimensional scanning of the target.

Hassard teaches a method of imaging molecules within a biological sample in two or three dimensional images (col. 3, lines 55-67; col. 4, lines 38-64). This method would reduce the time of imaging the results and increase the efficiency of large scale sequencing operations (col. 5, lines 10-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to analyze the gel of Ullman using the two and three dimensional scanning methods

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taught by Hassard for the advantages of reducing the time of imaging the results and increase the efficiency of large scale sequencing operations.

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

mct  
May 29, 2002

*Bao-Thuy L. Nguyen*  
BAO-THUY L. NGUYEN  
PRIMARY EXAMINER  
5/30/02